

## **REMARKS**

Examiner is thanked for withdrawing the Restriction Requirement. Claims 65-92 are pending. All claims stand rejected.

### **1. Claim Amendment for Typographical Error**

Claim 84 was amended to correct a typographical error by replacing “Claims” with “Claim”.

### **2. Claim Rejections Under 35 USC §112, 2<sup>nd</sup> Paragraph**

Claims 65-89 and 92 are rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being indefinite.

Claims 65, 66, 79, 80 and 85 stand rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being indefinite for failing to recite a positive process step. Claims 65, 66, 79, 80 and 85 have been amended to contain the language “wherein the presence of said active reporter protein indicates said [first/prey] test polypeptide interacts with said [second/bait] test polypeptide”. Accordingly, the indefiniteness rejection for Claims 65-89 has been obviated in this regard and withdrawal of the indefiniteness rejection for Claims 65-89 is requested. It is noted that this amendment merely clarifies the claim language and is not intended to include the preamble into a claim limitation.

Claims 67, 72-75 and 92 stand rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being indefinite. The Office Action asserted that it is unclear what constitutes the claim limitation “to at least partially anchor to the cell membrane” and that there is not a situation where the protein is sometimes anchored but sometimes not anchored. Applicants respectfully traverse the rejection on the grounds that the specification describes an example of a situation where the protein is partially anchored and is clear as to what constitutes the claim limitation “to at least partially anchor to the cell membrane.” Specifically, the specification at the last paragraph of page 39 provides that a “membrane anchoring domain can be a polypeptide that exhibits sufficient affinity to a cell surface protein or cell membrane component to effect binding of the molecule to the

surface of the cell membrane.” Binding of the molecule to the surface of the cell membrane describes a situation of partially anchoring to the cell membrane because the molecule will sometimes be bound and sometimes not bound due to the nature of molecular binding. In contrast, a polypeptide having a transmembrane spanning domain will be anchored to the cell membrane at all times. Therefore, Applicants request withdrawal of the indefiniteness rejection for Claims 67, 72-75 and 92 because the specification is clear as to what constitutes the claim limitation “to at least partially anchor to the cell membrane.”

Claim 89 is rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being inconsistent with the claim from which it depends (i.e., Claim 85) because Claim 85 indicates that the prey fusion protein comprises a C-intein and the bait fusion protein comprises an N-intein; whereas Claim 89 indicates that the prey fusion protein comprises an N-intein and the bait fusion comprises a C-intein. Claim 89 has been amended to be consistent with the claim from which it depends (Claim 85) by indicating that the prey fusion protein comprises a C-intein and the bait fusion protein comprises an N-intein. Accordingly, the indefiniteness rejection for Claim 89 has been obviated and withdrawal of the rejection is requested.

### **3. The Rejections Under 35 USC §102**

Claims 65-70, 72 and 90-92 are rejected under 35 U.S.C. 102(a) as being anticipated by Ozawa *et al.*, *Anal. Chem.*, 72:5151-5157 (2000).

Ozawa was published on the Web on September 29, 2000, and its physical form was published on November 1, 2000. As is clear from the concurrently submitted Rule 131 Declaration by Dr. John Manfredi (the inventor) and the attached Exhibits, both dates can be sworn behind. Nonetheless, Applicant notes that no admission is made or intended that September 29, 2000 is the reference date of Ozawa.

The Declaration shows that conception of the invention in Claims 65-70, 72, and 90-92 was completed prior to September 29, 2000 by Dr. John Manfredi. This is clearly evidenced by the invention disclosure in Exhibit A.

The Declaration also demonstrates that the Applicants were diligent in constructively reducing the invention to practice from a time prior to September 29, 2000

up until the filing date of the provisional application (U.S. Provisional Application Serial No. 60/259,759) from which the instant application claims benefit.

Specifically, Dr. John Manfredi diligently began the process of constructive reduction to practice prior to September 29, 2000 by submitting the invention disclosure in Exhibit A to the Legal Department of Myriad and requesting a patent filing. Continued diligence on the part of Myriad Legal Department, thereafter, in preparing and filing a patent application is also shown in the Declaration. Such diligence should be imputed upon the Applicants.

It is noted for the record that no admission is made or intended as to the exact date of conception except that the conception was completed prior to August 25, 2000, that is, prior to September 29, 2000. It is also noted for the record that no admission is made or intended as to the existence or date of any actual reduction to practice by the Applicant. However, it is believed that the above facts or data are sufficient to satisfy the requirements under 37 C.F.R. §1.131. Accordingly, Applicants request withdrawal of the rejection of under 35 U.S.C. 102.

#### **4. The Rejections Under 35 USC §103**

Claims 71, 80, 81, 85 and 86 stand rejected under 35 U.S.C. 103(a) as being obvious over Ozawa *et al.*, *Anal. Chem.*, 72:5151-5157 (2000), in view of Michnick *et al.* (US Patent No. 6,294,330), and further in view of Brent *et al.*, (US Patent No. 5,695,941). Neither Brent nor Michnick teaches a screening method for selecting protein-protein interaction modulators utilizing intein elements. Ozawa has been sworn behind by the attached Declaration. Accordingly, this rejection should be withdrawn.

#### **5. The Rejections Under Double Patenting**

Claims 65, 66, 90 and 91 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 2 and 23 of U.S. Patent No. 6,562,576 (the '576 patent). Applicants have overcome this rejection by filing the attached terminal disclaimer in compliance with 37 CFR 1.321(c). Accordingly, Applicants request that this rejection be withdrawn.

### CONCLUSION

In view of the above amendments and remarks, all claims are now in condition for allowance. An early notice to this effect is respectfully requested. The Examiner is invited and encouraged to call the undersigned if it may expedite the prosecution of this application.

Respectfully submitted,



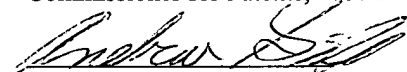
Andrew Gibbs  
Attorney for Applicant  
Registration No. 52,943

Intellectual Property Department  
**Myriad Genetics, Inc.**  
320 Wakara Way  
Salt Lake City, UT 84108  
Telephone: 801-584-3600  
Fax: 801-883-3871

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Andrew Gibbs

2-3-04  
Date